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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/649,108	08/28/2000	Lieping Chen	07039-220001	7772
26191 7590 11/13/2007 FISH & RICHARDSON P.C. PO BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER OUSPENSKI, ILIA I	
			ART UNIT 1644	PAPER NUMBER
			MAIL DATE 11/13/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 09/649,108	Applicant(s) CHEN, LIEPING	
	Examiner ILIA OUSPENSKI	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 6-10, 14-35, 38-42 and 45-62 is/are pending in the application.
- 4a) Of the above claim(s) 8, 10, 14-35, 38-42 and 45-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6, 7, 9 and 49-62 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/30/2007</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

1. Applicant's amendment and remarks, filed on 09/04/2007, are acknowledged.

Claims 52 – 62 have been added.

**Claims 6 – 10, 14 – 35, 38 – 42, and 45 – 62 are pending.**

Claims 8, 10, 14 – 35, 38 – 42, and 45 – 48 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected Inventions/Species, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 02/28/2002.

***Claims 6 – 7, 9, and 49 – 62 are under consideration in the instant application.***

The rejections of record can be found in the previous Office Action, mailed on 01/29/2007.

It is noted that New Grounds of Rejection are set forth herein.

2. Claim 6 is objected to because of the following informality: an apparent typographical error in the recitation of “65oC.”

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3. The following is a quotation of the **first paragraph of 35 U.S.C. 112**:

*The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.*

4. Claims 55 and 62 are rejected under **35 U.S.C. 112, first paragraph**, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. *This is a New Matter rejection.*

Applicant points to the specification at Figure 2A and at page 33 lines 28 – 31 for support for the newly added claims 55 and 62.

However, the specification does not appear to provide an adequate written description of the newly added claim limitations of polypeptides comprising the recited amino acid ranges. It is acknowledged that Figure 2A, when viewed in conjunction with the disclosure at page 33, shows that amino acid 234 is the last amino acid of the “Ig-C-like” domain, and amino acid 239 is the last amino acid of the extracellular domain of the polypeptide of SEQ ID NO:1. However, the specification as-filed does not appear to disclose that isolated polypeptides comprising the recited amino acid ranges are embodiments of the present invention. Furthermore, there does not appear to be an adequate support for the recitation of approximate ranges, i.e. from “about” amino acid 23 to “about” amino acid 239, etc.

The instant claims now recite limitations which were not clearly disclosed in the specification and claims as filed, and now change the scope of the instant disclosure as filed. Such limitations recited in the present claims, which did not appear in the

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specification or original claims, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the New Matter in the response to this Office Action. Alternatively, Applicant is invited to clearly point out the written support for the instant limitations.

5. Claim 6 is rejected under **35 U.S.C. 112, first paragraph**, because the specification, while being enabling for an isolated polypeptide encoded by the recited nucleic acid which hybridizes over its full length to the complement of a sequence encoding SEQ ID NO:1, does not reasonably provide enablement for the claimed polypeptide wherein the hybridization is not over the full length of the sequence. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification does not enable one of skill in the art to practice/make and use the invention as claimed without undue experimentation. Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, limited working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention.

The claim, as presently recited, reads of fragments of the polypeptide of SEQ ID NO:1, or of a polypeptide closely related in sequence to SEQ ID NO:1, because hybridization under the recited conditions can be accomplished by relatively short nucleic acid molecules, as one of skill in the art is aware. However, the specification

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does not appear to have provided sufficient guidance as to which subsequences of SEQ ID NO:1 would share the activity of SEQ ID NO:1, such as the ability to costimulate T cells. Neither does the specification appear to have provided any working examples of such functional subsequences. At the same time, it was well known in the art at the time the invention was made that numerous amino acids are essential to the function of costimulatory proteins. Even single amino acid differences can result in drastically altered functions of costimulatory proteins. For example, Metzler et al. (Nature Structural Biol. 1997; 4:527-531; of record) show that any of a variety of single amino acid changes can alter or abolish the ability of CTLA4 to interact with its ligands CD80 and CD86 (e.g., summarized in Table 2). Thus it is unpredictable which fragments defined by the hybridization language would be functional, and it would require undue experimentation of the skilled artisan to make and use such fragments.

The scope of the claims must bear a reasonable correlation with the scope of enablement. See In re Fisher, 166 USPQ 18 24 (CCPA 1970). "It is not sufficient to define the recombinant molecule by its principal biological activity, [...] because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property." Colbert v. Lofdah, 21 USPQ2d, 1068, 1071 (BPAI 1992).

6. The following is a quotation of the appropriate paragraphs of **35 U.S.C. 102** that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

*(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.*

7. Claims 6 – 7, 9, and 49 – 51 stand rejected, and newly added claims 52 – 62 are rejected under **35 U.S.C. 102(e)** as being anticipated by Freeman et al. (US Patent No. 7,038,013; of record; see entire document), for the reasons of record.

Applicant's arguments have been fully considered but have not been found convincing.

Applicant argues that the reference of Freeman et al. has not been properly established as prior art under 35 USC 102(e), because the particular part relied on in the provisional application of Freeman et al. has not been designated.

In response, the provisional application of Freeman et al., USSN 60/150,930, filed on 08/23/1999, discloses SEQ ID NO:4 e.g. in the Sequence Listing. This sequence is the same as disclosed in Patent No. 7,038,013, and is identical to the instantly recited SEQ ID NO:1, as addressed in the previous office action.

Therefore, the rejection of record is maintained for the reasons of record, as it applies to the amended and newly added claims. The rejection of record is incorporated by reference herein, as if reiterated in full.

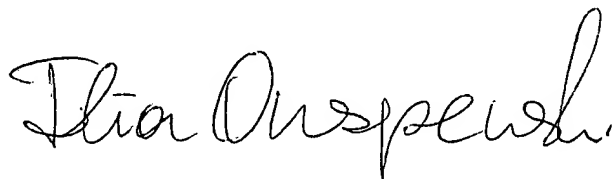
**8. Conclusion: no claim is allowed.**

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, reading "Ilia Ouspenski". The signature is written in a cursive, flowing style with a large initial 'I' and 'O'.

ILIA OUSPENSKI, Ph.D.

Patent Examiner

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November 1, 2007